

The opinion in support of the decision being entered today was **not** written for publication and is **not** binding precedent of the Board.

Paper No. 22

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex parte QUANG Q. TRAN, MARLOWE PATTERSON, HENRY NITA  
and PAUL C. SLAIKEU

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Appeal No. 2000-0447  
Application No. 08/838,685

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ON BRIEF

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Before NASE, CRAWFORD, and BAHR, Administrative Patent Judges.  
CRAWFORD, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 1 through 9, which are the only claims pending in this application.

The appellants' invention relates to a catheter having an elongate tubular member. An understanding of the invention can be derived from a reading of claim 1, which appears in the appendix to the appellants' brief.

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THE PRIOR ART

The prior art references of record relied upon by the examiner in rejecting the claims are:

Bodicky	4,333,455	June 8, 1982
Heyman	4,571,239	Feb. 18, 1986
Amiel	5,342,350	Aug. 30, 1994
Mikhail et al. (Mikhail)	5,624,395	Apr. 29, 1997
Gore et al. (Gore)	5,662,622	Sep. 2, 1997

THE REJECTIONS

Claims 1, 7 and 8 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Gore.

Claim 2 stands rejected under 35 U.S.C. § 103 as being unpatentable over Gore in view of Mikhail.

Claims 3 and 4 stand rejected under 35 U.S.C. § 103 as being unpatentable over Gore in view of Amiel.

Claim 5 stands rejected under 35 U.S.C. § 103 as being unpatentable over Gore in view of Heyman.

Claim 6 stands rejected under 35 U.S.C. § 103 as being unpatentable over Gore.

Claim 9 stands rejected under 35 U.S.C. § 103 as being unpatentable over Gore in view of Bodicky.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellants regarding the above-noted

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rejections, we make reference to the answer (Paper No. 15) for the examiner's complete reasoning in support of the rejections, and to the brief (Paper No. 14) for the appellants' arguments thereagainst.

#### OPINION

In reaching our decision in this appeal, we have give careful consideration to the appellants' specification and claims, the applied prior art references, and to the respective positions viewpoints articulated by the appellants and the examiner. As a consequence of our review, we make the determinations which follow.

We turn first to the examiner's rejection of claims 1, 7 and 8 under 35 U.S.C. § 102(e) as anticipated by Gore. The examiner found that Gore discloses:

. . . a catheter with a proximal section (25) that has a tapered joint (40) that joins the intermediate section (26). The intermediate section has a tapered joint (39) that joins the distal section (27&28), see fig. 1. The flexibility of the catheter increase from the proximal end of the catheter tube (18) to the distal end (16), see col. 4, lines 47-50. The distal portion (27&28) has a relatively constant diameter, and there is another portion of the distal section (28) that has a different diameter. [answer at pages 3-4].

Appellants argue that Gore does not anticipate claim 1 because Gore does not disclose a blood-flow directable catheter.

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Appellants are of the opinion that the preamble of claim 1 from which claims 2 through 9 depend breathes life and meaning into the claim.

The examiner argues that the term "blood-flow directable catheter" is ambiguous and as such does not breath life into the meaning of the claim in terms of a structural limitation. The examiner further states that even if this term in the preamble does breath life and meaning into the claims, the structural limitations of a flow directed catheter as defined by appellants are taught by Gore.

We note at the outset that the question of whether a preamble constitutes a limitation to a claim is a matter to be determined by the facts of each case in view of the claimed invention as a whole. See In re Stencel, 828 F.2d 751, 754, 4 USPQ2d 1071, 1073 (Fed. Cir. 1987). The preamble of a claim does not limit the scope of the claim when it merely states intended use of the invention. In re Pearson, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974). However, terms in a preamble are construed as limitations when they give life and meaning to the invention claimed. Gerber Garment Technology, Inc. v. Lectra Syst., Inc., 916 F.2d 683, 688, 16 USPQ2d 1436, 1441 (Fed. Cir. 1990) (quoting) Perkins-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 896, 221 USPQ 669, 675 (Fed.

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Cir.), cert. denied, 469 U.S. 857 (1984). Although no "litmus test" exists as to what effect should be accorded to terms appearing in a preamble, a patent application in its entirety should be reviewed to determine whether the inventors intended such language to represent additional limitations or mere introductory language. See, e.g., In re Paulsen, 30 F.3d 1475, 1479, 31 USPQ2d 1671, 1673-74 (Fed. Cir. 1994) (citing Corning Glass Works v. Suitomo Elect. U.S.A., Inc., 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989)).

A review of appellants' specification reveals that appellants' flow directed catheter is so flexible at its distal end and mid regions that it is carried by blood flowing to a target site (specification at page 2). The appellants' specification further discloses that the distal end therein disclosed is made of polymer which is inherently quite springy and flexible and biologically compatible such as polyvinylchloride (specification at page 4). Regarding the softness of the distal end, appellants' specification discloses that the distal end has a hardness of between 60A and 70A shore.

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Appellants have also filed a declaration executed<sup>1</sup> by Henry Nita which states:

It is well known in the practice of medicine that flow-directed catheters are a class of catheters considered separate from guidewire-directed catheters. Flow-directed catheters are comparatively more flexible and are positioned at a target site by the flow of blood. In contrast, typically stiffer guidewire-directed catheters are pushed over a guidewire to a target site. [Nita declaration at page 2].

The appellants have filed a copy of Juan M. Taveras, MD, Neuroradiology, (Waverly Company), Chapter 18.2, page 1050, which states:

Flow-directed microcatheters have a very soft, floppy, distal segment that is carried by the blood flow (16). The stiff proximal portion allows the distal segment to be advanced through the catheter. ... With these catheters it is usually possible to reach almost any vessel, even those with very small flows, by using the appropriate curve and manipulation.

In view of the foregoing, it is our view that the term "flow directed catheter" is a catheter with a distal end which is so soft that it can be carried to the target site by blood. As such, the term "flow directed catheter" is not ambiguous.

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<sup>1</sup> The appellants filed this declaration with the reply brief in response to the arguments made by the examiner for the first time in the answer. As the reply brief, Nita declaration and Taveras article were all filed and entered as a single paper (Paper No. 17), we interpret the examiner's statement in Paper No. 18 as an approval of the entry of the reply brief and attached declaration and article.

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In addition, in our view, the phrase in the preamble of claim 1 i.e., "blood-flow directable catheter" is a catheter constructed of materials and having a size and flexibility such that the catheter is directable to a target site by blood flow and as such the "blood-flow directable catheter" does breath life and meaning into claim 1.

To support a rejection of a claim under 35 U.S.C. § 102(e), it must be shown that each element of the claim is found, either expressly described or under principles of inherency, in a single prior art reference. See Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 772, 218 USPQ 781, 789 (Fed. Cir. 1983), cert. denied, 465 U.S. 1026 (1984). The prior art reference need not expressly disclose each claimed element in order to anticipate the claimed invention. See Tyler Refrigeration v. Kysor Indus. Corp., 777 F.2d 687, 689, 227 USPQ 845, 846-847 (Fed. Cir. 1985). Rather, if a claimed element (or elements) is inherent in a prior art reference, then that element (or elements) is disclosed for purposes of finding anticipation. See Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 631-33, 2 USPQ2d 1051, 1052-54 (Fed. Cir.) cert. denied, 484 U.S. 827 (1987).

It is well settled that the burden of establishing a *prima facie* case of anticipation resides with the Patent and Trademark

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Office (PTO). See In re Piasecki, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984). When relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. See Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed Cir. 1991); Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Int. 1990).

After the PTO establishes a *prima facie* case of anticipation based on inherency, the burden shifts to the appellant to prove that the subject matter shown to be in the prior art does not possess the characteristics of the claimed invention. See In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985); In re King, 801 F.2d 1324, 1327, 231 USPQ 136, 138 (Fed. Cir. 1986). Gore discloses a intravascular catheter which has a proximal section which has a softness of 75A shore. The appellants' catheter has a distal section with a softness between 55A and 75A shore. Gore discloses a midsection with a softness of 65A shore. The appellants' midsection has a softness between 65A and 85A shore. Gore's distal end has a softness of 80A shore. Appellants disclose a distal end with a softness between

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55A and 75A shore. Gore discloses that the distal portion is comprised of a polyurethane (col. 5, lines 29 to 41). In addition, as argued by the examiner:

. . . the diameter of the proximal section of Appellants' catheter is typically between 2.9 F and 3.5 F. Similarly, the diameter of proximal section of the Gore catheter is 3 F. The diameter of the distal section of Appellants' catheter is preferably between 1 F. and 2.5 F. Similarly, the diameter of the distal section of the Gore catheter is 2.5 F. [answer at pages 8 to 9]. The examiner further states that:

Furthermore, even if one considers the phrase to "breathe life and meaning," those limitations incorporated from Appellants' Specification concerning materials and sizes are either identical to or very similar to those of Gore et al. [answer at page 10].

In essence the examiner argues that the Gore catheter is inherently flow directable. While it is possible that the Gore catheter may be flow directable because of the identity of the size of the catheter and the similarity in the shore hardness of the various sections of the catheter, mere possibilities are not enough. The Gore disclosure does not mention flow directability. The shore hardness of the Gore distal section which is an important in view of the feature of flow directability is 80 A while the disclosed distal section has a shore hardness of 55A to 75A (specification at page 5). In addition, the Gore catheter is provided with by a helical coil reinforcement 42 which may affect the flexibility and

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thus the ability to be flow directed of the Gore catheter. Therefore, we are of the opinion that the finding that the Gore catheter is flow directable is speculative. Inherency, however, can not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. Id., 948 F.2d at 1269, 20 USPQ2d at 1749 (quoting In re Oelrich, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981)). As such, the examiner has failed to establish a *prima facie* case of anticipation by inherency and we will therefore not sustain this rejection.

We will likewise not sustain the remaining references as these references do not cure the deficiency noted above for the Gore reference.

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The decision of the examiner is reversed.

REVERSED

JEFFREY V. NASE	)	
Administrative Patent Judge	)	
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	)	
	)	BOARD OF PATENT
MURRIEL E. CRAWFORD	)	APPEALS
Administrative Patent Judge	)	AND
	)	INTERFERENCES
	)	
	)	
	)	
JENNIFER D. BAHR	)	
Administrative Patent Judge	)	

MEC/jrg

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